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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,292

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Zhiqiang Gao

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW

PO BOX 14329

RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1657

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/577,292	<b>Applicant(s)</b> GAO ET AL.	
	<b>Examiner</b> Ralph Gitomer	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 46-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

The amendment received 11/20/08 has been entered and new claims 46-56 are currently pending in this application. The amended title and abstract are acceptable. In claim 49 the second word may be a typo.

In view of the new claims and arguments submitted, the rejections of record under 35 USC 112, first and second paragraphs, are hereby withdrawn.

A reading of the specification reveals the point of novelty may reside in making vinylferrocene acrylamide copolymers for glucose sensors where the ferrocene does not interfere with polymerization while in sufficiently high concentration. The size of the ferrocene does not appear to be of any functional consequence.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 46-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rauh in view of Bu.

Rauh (5,922,183) entitled "Metal Oxide Matrix Biosensors" teaches in column 4, a thin film containing amorphous hydrous metal oxides including Ti, Zr, Ru, Pd, Pt, Zr, Ti. Rh. In column 8 last paragraph bridging to column 9, electron mediators can be co-immobilized into the matrix and include ferrocene and derivatives. The film is used for determining glucose. See the claims.

The claims differ from Rauh in that they specify the matrix is an acrylamide polymer.

Bu (Anal Chem) entitled "Modification of Ferrocene Containing Redox Gel Sensor Performance by Copolymerization of Charged Monomers" teaches on page 3951 column 1 first paragraph, a glucose determining electrode with glucose oxidase and ferrocene formed by copolymerization of vinylferrocene hydroxypropyl cyclodextrin inclusion complex, acrylamide and N,N'-methylenebis(acrylamide). On page 3852 column 1 first paragraph polyvinyl ferrocene is shown.

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the components of a glucose biosensor as taught by Rauh in a polymeric matrix such as that taught by Bu because polymeric matrices are conventional in this art and Bu teaches the same types of components in the matrix for the same function as claimed. Note that the amorphous oxides in Rauh would be nanoparticles. And Bu teaches the same polymer matrix as claimed with the same glucose oxidase and sufficient ferrocene to function as a glucose sensor.

Applicant's arguments filed 11/20/08 have been fully considered but they are not persuasive.

Applicants response argues that the present claims require the enzyme and mediator are diffusibly dispersed in the membrane which is not taught in either reference cited. In Rauh the enzyme becomes trapped in the matrix. Rauh describes advantages to the invention disclosed which would thereby not motivate one to alter it. Bu does not describe the presently claimed nanoparticle membrane.

It is the examiner's position that the membrane of Rauh teaches substances including the same enzymes and mediators as presently claimed are diffusibly dispersed within the membrane. Fig. 1 of Rauh shows the enzyme is dispersed within the membrane. In column 4 last paragraph bridging to column 5, co-immobilization of biomolecules in the membrane is described. In column 6 lines 18-28, various methods of immobilizing the enzyme in the membrane are discussed including absorption, electrodeposit from a solution. In column 11 lines 33-36, the enzyme is deep in the matrix and access is disclosed. In column 12 lines 34-51, enzyme loading in the membrane is considered regarding the charges. It would seem this description of the dispersion of the enzyme in the matrix would be encompassed by diffusibly dispersed. Further, for the membrane to function, the analyte must have contact with both the enzyme and the mediator and for the reactions to continue beyond initial contact, the enzyme and mediator must be maintained in such a fashion that the contacting continues for the desired time period. Bu was cited to show the acrylamide polymer with polyvinyl ferrocene for sensor membranes and the function of the material. No

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novelty is seen in constructing sensor membranes with polyvinyl ferrocene in view of Bu.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/  
Primary Examiner, Art Unit 1657

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